CCTSI Update - 2020
Town Hall

Ronald J. Sokol, MD
Director and P.I. of CCTSI
Assistant Vice Chancellor of Clinical and Translational Science
University of Colorado – Anschutz Medical Campus
CTSA Program

• An NIH-funded national consortium of biomedical research institutions collaborating to transform how clinical and translational science is conducted nationwide

• Currently, 60 funded Hubs, many of which include multiple universities and hospitals.

• CTSAs provide many local resources, facilities, research personnel, pilot funding, regulatory and informatics support, research units and education & training programs

• Grants originate from NCATS at NIH
Colorado Clinical & Translational Sciences Institute

- CCTSI is the Colorado CTSA Hub
- Created in 2008, refunded in 2013, 2018
- Substantial institutional support (funding)
- Supports all faculty, post-docs, trainees involved in clinical or translational research at 3 universities and 6 hospital partners
- “Disease – agnostic”
- Infrastructure, facilities, education and training, pilot grant funding, special functions and more
CCTSI Vision

Accelerate and catalyze the translation of innovative science into improved health and patient care
CCTSI 3.0 Mission

• **Catalyze** and enhance scientific discovery, innovation, dissemination and translation across the lifespan

• **Educate** and sustain a resilient, innovative and diverse translational science workforce

• Promote and ensure an efficient, safe, collaborative and integrated research environment

• **Engage stakeholders and communities** across the entire translational spectrum
Spectrum of Translational Research

Clinical Translational Research Spectrum

- Bi-Directional
- Collaboration
- Team Science

T0.5
- Basic Scientific Discovery
- Translation to Natural Animal Models

T1
- Preclinical Insights
- Translation to Humans

T2
- Clinical Insights
- Translation to Patients
- Implications for Practice
- Translation to Practice

T3
- Implications for Population Health
- Translation to Population

T4
- Improved Global Health

Images:
- Test tube
- Dog
- Brain scan
- Medical professionals
- Global icon
CCTSI Membership

CCTSI Monthly Membership Growth

CCTSI Membership by Academic Affiliation

- Missing or Not reported
- Colorado State University
- Kaiser Permanente of Colorado
- Other
- University of Colorado Anschutz Medical Campus
- University of Colorado Boulder
- University of Colorado Denver

6,505
CCTSI Leadership

**Director:** Ronald Sokol, MD  
**DFA:** Tim Lockie, MS, MBA

**Director of Operations:** Janine Higgins, PhD

**Associate Directors:**
- Wendy Kohrt, PhD
- Tell Bennet, MD, MS
- Alison Lakin, RN, JD
- Donald Nease, MD, MPH
- Thomas Campbell, MD
- Lisa Cicutto, PhD

**CSU:** Susan VandeWoude, PhD  
**CU- Boulder:** Chris Desouza, PhD
CCTSI Programs & Resources

1. Education, Training and Career Development – KL2, TL1, CLSC, LITeS, etc.
2. Clinical Research Resources & Facilities (CTRCs – inpt., outpt., mobile; CReST)
3. Community Engagement & Research – Don Nease
4. Dissemination – Implementation Research – Bethany Kwan, PhD
5. Team Science – Jeni Cross, PhD
6. Biostatistics, Epidemiology and Research Design – CIDA (Nichole Carlson, PhD)
7. Translational Informatics – Tell Bennett, MD, MS
8. Research Bioethics – Marilyn Coors, PhD
9. Regulatory Knowledge and Support – Alison Lakin JD, RN
10. Pilot Grant Programs – Natalie Serkova, PhD
11. Trial Innovation Network – Hub Liaison Team
12. Innovation and Entrepreneurship – Cathy Bodine, PhD
13. Early Life Exposures Program (ELEP) Research – Teri Hernandez, PhD
CCTSI Website

- [https://cctsi.cuanschutz.edu/](https://cctsi.cuanschutz.edu/)
  or “Google” CCTSI

- Portal of entry
  - Information, applications, links to services, RFAs, training, announcements, etc.

- **Membership online** – quarterly Newsletter (Found in Translation – Wendy Meyer)

- Colorado Profiles

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**WEBSITE:**
6,000 - 7,000 visits per month

**PROFILES:**
15,000 – 20,000 visits per month
ACCELERATING RESEARCH TO IMPROVE HEALTH

The CCTSI helps build research teams of the future, speed the development of new treatments and improve human health.
Resources and Services
CCTSI supports translational research by providing resources, integrating facilities and services, developing innovative research tools and catalyzing interdisciplinary research programs.

Funding
Each year, the CCTSI awards more than $2 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards. You can find more information on each grant and how to apply.

Education, Training and Career Development
The Education, Training and Career Development (ETCD) program provides clinical-translational scientists and trainees with knowledge, training and career skills.

Clinical Translational Research Centers
The CTRC provides infrastructure, resources and dedicated space to conduct clinical research.

Cite our grant
Become a member
Join the CCTSI for free

Find a researcher
Colorado PROFILES

Mapping Our Molecules »
Jun 25, 2019, 12:00 AM by Wendy Meyer
Why know that exercise is good for us, Professor Wendy Kohrt aims to find out why. She is leading an exercise study called MoTIPAC to develop a so-called molecular map of tissue-specific and circulating signals produced by physical activity.

Full story »
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Full story »
Search for Investigators by Key Words
Search Colorado PROFILES

The “Colorado PROFILES” search engine for biomedical research expertise and networking provides tools to help investigators and students find experts, potential collaborators or mentors, and to view past and present research networking of our investigators.

Find people by research topic

Keywords: biliary atresia

Search

Find people by name/organization

Last Name
First Name
Institution
Department
Faculty Type

Search
Ranked List of Researchers At CU

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>Why</th>
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<tbody>
<tr>
<td>Cara Lynn Mack</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
<td>Why?</td>
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<tr>
<td>Ronald J Sokol</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
<td>Why?</td>
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<td>Frederick M Karrer</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
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<td>Amy G. Feldman</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
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<td>Shikha Seksaria Sundaram</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
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<td>Rebecca Michelle Tucker</td>
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<td>Frederick J Suchy</td>
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<td>Michael R Narkewicz</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
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<td>Alexandra Leigh Kilgore</td>
<td>University of Colorado Denver - Anschutz Medical Campus</td>
<td>Why?</td>
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The "Colorado PROFILES" search engine for biomedical research expertise and networking provides tools to help investigators and students find experts, potential collaborators or mentors, and to view past and present research networking of our investigators.

Find People
Find Research

Search for Investigators by Name, Institution, Department, or Faculty Type
Results: Contact info, Grants, Publications from PubMed, Networking
Clinical Translational Research Centers (CTRCs)

- UCH, CHCO, NJH, CU-B and Perinatal
  - Inpatient and outpatient facilities – no charge for space (industry studies excluded)
  - Research Nursing – inpatient, outpatient, mobile teams (NICU, PICU, ED, etc.) – subsidized fee for service
  - Bio-nutrition, metabolic kitchen, whole room calorimeter and body composition
  - Vascular Ultrasonography and ECHO
  - Core laboratories & specimen processing
  - Microgrants to Jr. Investigators ($10,000/yr. x 3)
  - SARC review of all protocols
  - 200 unique PI’s conduct research on >500 CTRC Protocols each year (10,000-15,000 visits/yr)
CTRC Medical Directors

- **UCH/Adult** – Thomas Campbell, MD
- **CHCO/Pediatrics** – Phillip Zeitler, MD, PhD
- **Perinatal** – Christopher Baker, MD
- **NJH** – Donald Leung, MD, PhD
  [https://www.nationaljewish.org/research-science/clinical-and-translational-research/ctrc](https://www.nationaljewish.org/research-science/clinical-and-translational-research/ctrc)
- **CU-Boulder** – Chris DeSouza, PhD and Brian Stauffer, MD
  [https://www.colorado.edu/ctrc/](https://www.colorado.edu/ctrc/)
Pilot Grant Awards
Natalie Serkova, PhD

- **5 Pilot Grant programs** – CO-Pilot, CMH, Community Engagement, New Methods, CU-CSU Collaboration Award
- ~$900,000 available
- $20,000, 30,000, $60,000 levels
  - Letter of Intent in August
  - Deadline September (end)
  - Peer Review in November-December
  - Start-up in January-April
CCTSI Rapid Turn-Around COVID-19 Pilots

- March, 2020: CCTSI leadership developed $100,000 C2R2 Pilot Grant Program and issued RFA in 3 days; applications due in 7 days
- 60 letters of intent received; 55 applications received
- Review committee: 22 experts across affiliated institutions (reviews completed in 4 d)
- Awards issued and speedtypes activated and funded 3 days later

<table>
<thead>
<tr>
<th>PI Affiliation Project Title</th>
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<tbody>
<tr>
<td>David Prawel, PhD Colorado State University Additive Manufacturing of Certified PPE: A Path Towards Mass Production</td>
</tr>
<tr>
<td>J. David Beckham, MD Anschutz Medical Campus A prospective, observational cohort trial for the treatment of hospitalized COVID19 patients with high-titer anti-SARS-CoV2 convalescent serum</td>
</tr>
<tr>
<td>Anna Maw, MD Anschutz Medical Campus Rapid Point of Care Lung Ultrasound Implementation in the Evaluation of Hospitalized Patients with COVID</td>
</tr>
<tr>
<td>Brian Montague, DO Anschutz Medical Campus Prospective Identification of SARS-CoV2 Infection in Healthcare Workers</td>
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Translational Informatics
Tell Bennett, MD, MS

• **REDCap** – operated for entire campus by CCTSI – >9,000 users, >6,000 active projects

• **Health Data Compass** – enterprise-wide research data warehouse – Michael Kahn, MD, PhD Previous Director

• Colorado **PROFILES**, Scheduler, Harvest, LIS, Freezerworks

• **Data Delivery & Cohort Discovery** – TrinetX, Compass, ACT, N3C

• **Multiple applications** to support Grant Review and Education programs
Translational Informatics Team

• **Director:** Tell Bennett, MD, MS
• **REDCap team**
  Amanda Miller, REDCap Senior Administrator and Team Lead
  Jenn Mauck, REDCap Administrator
• **Infrastructure and Services Team**
  Tom Yaeger, Director
  Melanie Tsosie, Associate Director and Applications Specialist
  Chris Caldwell, Web Manager
  Matt Latus, Information Security Officer
  Ambreen Zaver, Developer
  Open Position, Systems Administrator
National COVID Cohort Collaborative (N3C)

- A centralized, secure portal for hosting national patient-level COVID clinical EHR data and deploying statistical methods and tools for clinicians, researchers, and healthcare – to answer pressing clinical and research questions

- **EHR data (UCH, CHCO)** entered by CTSA program institutions, distributed clinical data networks (e.g., PCORnet, OHDSI, ACT/i2b2, and TriNetX), and many other clinical partners and collaborators

- [https://ncats.nih.gov/n3c](https://ncats.nih.gov/n3c)
# Key N3C Stats – 6 Dec 2020

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Positive Patients*</td>
<td>372,716</td>
</tr>
<tr>
<td>Total Patients</td>
<td>2,146,059</td>
</tr>
<tr>
<td>Sites</td>
<td>34</td>
</tr>
<tr>
<td>Total Rows</td>
<td>2.0b</td>
</tr>
<tr>
<td>Procedures</td>
<td>152.5m</td>
</tr>
<tr>
<td>Lab Results</td>
<td>955.0m</td>
</tr>
<tr>
<td>Drug Exposures</td>
<td>359.1m</td>
</tr>
<tr>
<td>Visits</td>
<td>92.0m</td>
</tr>
<tr>
<td>Observations</td>
<td>120.6m</td>
</tr>
</tbody>
</table>

Click to see more COVID Cohort key stats >
N3C Data Enclave Access

- Researchers can access the **N3C Data Enclave**, a centralized national COVID-19 data analytics platform to enable the rapid

Contact Tell Bennett, MD, MS - Informatics Core for more details and access

Secure data platform with powerful analytics capabilities
- Data – robust in scale and scope
- Harmonized data set
- Video: [https://www.youtube.com/watch?v=0JPjw1_iRKY](https://www.youtube.com/watch?v=0JPjw1_iRKY)
1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=14)

2. TL1 (T32) Pre- and Post-doctoral PhD training program

3. Clinical Sciences Graduate Program (Masters, PhD)

4. KL2 (K12) Research Scholar program - up to 3 yrs. of support – Ellen Burnham, MD

5. Support for Clinical Faculty Scholars Program – Anne Libby, PhD

6. Clinical Research Training and Education Program (CRSC)
8. Leadership in Innovative Team Science (LITeS) – Judith Albino
10. K-to-R Transition Grant Review – Maggie Wierman MD
11. Pre-K Award Assistance and Grant Review – Paul MacLean, PhD
12. Research Studios – Jane Reusch MD, Alan Prochazka MD
13. Innovation Corps @ CCTSI – Cathy Bodine, PhD
14. Teaming for Early Career Researchers – Jeni Cross, PhD
Pre-K Grant Review Program

• Assist junior faculty and their mentors write successful career development awards
  – 5 criteria (candidate, career development, mentors, environment, and research plan)

• Mock grant reviews: 3 times a year
  – Applicants and mentors attend
  – K24 awardees, K12 directors, biostats, other K awardees are reviewers
  – Format: reviewers and then panel discusses, followed by Q&A

• Helpful materials on website relevant to K applicants

Letter of Intent due December 28, 2020
K to R Transition Program

- Pre-submission mock grant review process
- Faculty with K-level awards who are submitting first R-level grant award or any R-level grant submission
- Submit grant proposal for internal review about 4-6 weeks before submission to funding agency
  - Deadline for Letter of Intent
- Mock study section and written reviews
- PI and mentor - attend mock study section
- 3 cycles – NIH grant application deadlines

- Maggie Wierman, MD  303-724-3952
Research Studio Program
Jane Reusch, MD and Alan Prochazka, MD

• **Expert Panel** (5-6 person) formed to provide targeted advice about research project, grant application, idea generation, etc.

• T1-T2 or T3-T4 research topics

• **Studio sessions** are Face to Face (over Lunch)
  - 90 Minutes
    - Investigator presents brief summary (10-15 minutes)
    - Focused discussion with experts for 3 or 4 predetermined questions from the investigator - focus on problem-solving and the development of helpful solutions (60-70 minutes)
    - Moderator and panelists provide summarized comments (10-15 minutes)
Research Studio Process

• Web-based Consult Request – CCTSI website
• Studio Consult Categories:
  ❖ hypothesis generation
  ❖ study design – specific aims
  ❖ grant review
  ❖ implementation
  ❖ analysis and interpretation
  ❖ manuscript review
  ❖ translation
Research Studio Dates

• Next Dates: Jan. 28, April 1, June 4 (4-5 Studios per session)

• Contact:

  Dan Holtrop, MA
  Studio Program Manager
  Daniel.Holtrop@cuanschutz.edu

Excellent feedback and usefulness
"Very beneficial service and significantly improved the quality of my research project"
- Investigator
i-Corps@CCTSI
Cathy Bodine, PhD

• i-Corp @ CCTSI

• Teams of faculty, staff or students with a biomedical discovery or health innovation idea.

• Uses customer discovery methods for startups for academic researchers

• A team-based short course designed for faculty, staff and students

• Guides teams through early stages of customer discovery

• Test the business model hypotheses for a technology or idea

• Spring 2021 session - website
Innovation & Entrepreneurship Ecosystem at AMC

A virtuous cycle of innovation and entrepreneurship

- Launch
- AMC Accelerator
- Pitch Competitions
- Incubating
- Vetting
- Idea Generation and Team Formation
- Entrepreneurial Education Curriculum and Culture

Technology Transfer Office

Accelerating

Opportunity Identification

CCTSI

Fundamentals

I-Corps @NCATS Team Training Pilot Program
Community Engagement & Research Programs

Don Nease, MD

- Community Research Liaison (CRL) program
- Colorado Immersion Training in Community Engagement (CIT)
- Research Readiness Certification for Community Based Organizations
- Community Engagement Consults
- CE Pilot Grant Program
- Boot Camp Translation for Patient-Centered Outcomes: Facilitator Training
- Introduction to CBPR for Community-Academic Partnerships
Trial Innovation Network (TIN)  
triaлинnovationnetwork.org

• National CTSA Consortium effort to facilitate design and conduct of Multi-Site (NIH) Clinical Trials

• Provides local and national support for the entire study lifespan
  • Study design, central IRBs, study operations, data collection and analysis, recruitment and retention strategies, etc.
  • TIN Hub Liaison Team – Local linkage to national TIN

• Investigators can request a single service (e.g., single IRB) or complete study life cycle assistance

• First contact the Hub Liaison Team for assistance and guidance
Trial Innovation Network Hub Liaison Team

- **Director:** Adit Ginde, MD
- **Medical Directors:** Tom Campbell, MD (UCH)  
  Jesse Davidson, MD (CHCO)
- **Project Manager – Aaron Mobley PhD**  
  **Phone:** 720-848-5523  
  aaron.mobley@cuanschutz.edu
- **Contracting Lead** – Deb Barnard, MS, TK Keith, JD
- **Central IRB Lead** – Christy Williamson
- **Recruitment (Participants) Lead** – Barbara Hammack

Local TIN Website, workflow, educational materials, etc.
RKS - Clinical Research Support Center (CRSC) – Alison Lakin, RN, JD

- FDA submissions
- Education and training on all aspects of study start up and management
- Assistance with IRB submissions
- Access to and maintenance of ClinicalTrials.gov records
- Research agreements (confidential disclosure agreements, clinical trial agreements and materials transfer agreements)
- Study drug/device management advice
- OnCore, the clinical trials management system

https://research.cuanschutz.edu/crs
Anschutz Health Sciences Building

- Planned occupancy Fall 2021
- All CCTSI Leprino 3rd Floor operations moving to 6th floor
- Two large procedure rooms (~300sf) to accommodate some activity that is currently performed IP
- Two negative pressure rooms
- Five chair infusion suite
- Building will have a dedicated research pharmacy
Diversity, Equity, Inclusion, Systematic Racism

- Education of CCTSI Staff
- Leadership education and commitment
- Position statement of commitment - accountable
- Expanding diversity of Leadership
- Incorporation of Community Members in CCTSI oversight committees
- Address inequities through CE&R program, pilot grant awards
- Diversity supplements
CCTSI is here to support you!

- https://cctsi.cuanschutz.edu or google CCTSI
- Become a Member (quick, free, powerful)
- Become familiar with the website
- Use PROFILES often
- Cite our Grants
QUESTIONS?